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APPLICATION NO. ATTORNEY DOCKET NO. 10/630,227 3518.1015-000 FIRST NAMED INVENTOR FILING DATE Thomas M. DiMauro July 30, 2003

EXAMINER Lee, Betty L. CONFIRMATION NO. 8291

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	U.S. PATENT DOCUMENTS						
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT			
CHY	Al	2003/0039651 A1	02-27-2003	Olmarker			
	A2	6,419,944 B2	07-16-2002	Tobinick			
	A3	2003/0049256 A1	03-13-2003	Tobinick			
	A4	2002/0026244 A1	02-28-2002	Trieu			
	A5	5,095,037	03-10-1992	Iwamitsu et al.			
	A6	6,049,026	04-11-2000	Muschler			
	A7	5,231,024	07-27-1993	Moeller et al.			
	A8	6,284,471 B1	09-04-2001	Le et al.			
	A9	5,447,851	09-05-1995	Beutler et al.			
	A10	5,116,964	05-26-1992	Capon et al.			
	A11	5,225,538	07-06-1993	Capon et al.			
	A12	6,277,969 B1	08-21-2001	Le et al.			
	A13	6,541,477 B2	04-01-2003	Goehring et al.			
	A14	5,965,583	10-12-1999	Beers et al.			
	A15	5,728,396	03-17-1998	Peery et al.			
7	A16	5,270,300	12-14-1993	Hunziker			
	A17	6,294,170 B1	09-25-2001	Boone et al.			
	A18	2001/0016195 A1	08-23-2001	Tobinick			
	A19	5,368,841	11-29-1994	Trauner et al.			
	A20	4,427,649	01-24-1984	Dingle et al.			
V	A21	5,656,272	08-12-1997	Le et al.			
Y				·			
1							

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DATE CONSIDERED

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PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 3518.1015-000	PLICATION NO. /630,227		
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		F	OREIGN PATENT D	OCUMENTS		
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
GMS	ВІ	EP 1153607 A2	11-14-2001	Dunn		
1	B2	WO 03/000190 A2	01-03-2003	DePuy		
	В3	WO 02/057240 A1	07-25-2002	Ortho Mc Neil Pharmaceutical, Inc.		
	B4	WO 91/02078	02-21-1991	Peptide Technology LTD		
	В5	EP 0 218 868 A2	04-22-1987	New York Blood Center, Inc.		
	В6	EP 0 288 088 B1	10-26-1988	Teijin Limited		
	B7	WO 92/07076	04-30-1992	The Charing Cross Sunley Research Centre		
	В8	WO 2004/022078 A1	03-18-2004	The Royal Veterinary College		
	B9	WO 97/28828	08-14-1997	Amgen Boulder Inc.		
	B10	WO 92/16553	10-01-1992	New York University		
	B11	WO 98/24477	06-11-1998	Amgen Inc.		
	B12	EP 1 133 995 A2	09-19-2001	Synergen, Inc.		
	B13	WO 01/85179 A2	11-15-2001	Clemson University		
1	B14	EP 0 438 234 A1	07-24-1991	Kita		

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PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. APPLICATION NO. 3518.1015-000 10/630,227			
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October 11, 2005 (Use several sheets if necessary)	EXAMINER Lee, Betty L.	CONFIRMATION NO. 8291		GROUP 1647

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
(A)	CI	Braun, J. and Sieper J., "Overview of The Use of The Anti-TNF Agent Infliximab in Chronic Inflammatory Diseases," <i>Expert Opin. Biol. Ther.</i> 3(1):141-168 (2003).				
	C2	Braun, J., et al., "Anti-Tumour Necrosis Factor α Therapy for Ankylosing Spondylitis: International Experience," Ann. Rheum. Dis., 61(Supp. III):iii51-iii60 (2002).				
	СЗ	Olmarker, K. and Rydevik, B., "Selective Inhibition of Tumor Necrosis Factor- α Prevents Nucleus Pulposus-Induced Thrombus Formation, Intraneural Edema, and Reduction of Nerve Conduction Velocity," Spine, 26(8):863-869 (2001).				
	C4	Aoki, Y., et al., "Local Application of Disc-Related Cytokines on Spinal Nerve Roots," Spine 27(15): 1614-1617 (2002).				
	CS	Tobinick, E.L. and Britschgi-Davoodifar, S., "Perispinal TNF-Alpha Inhibition for Discogenic Pain," Swiss Med. Weekly, 133:170-77 (2003).				
	C6	Maeda, S. and Kokubun, S., "Changes With Age in Proteoglycan Synthesis in Cells Cultured <i>In Vitro</i> From the Inner and Outer Rabbit Annulus Fibrosus," <i>Spine</i> , 25(2):166-169 (2000).				
	C7	Igarashi et al., Inflammatory Cytokines From Facet Joint Tissue in Degenerative Lumbar Disorder, ISSLS Abstract #262 (May 13-17, 2003).				
	C8	Wittenberg, et al., "In Vitro Release of Prostaglandins and Leukotrienes From Synovial Tissue, Cartilage, and Bone in Degenerative Joint Diseases," Arthritis Rheum., 36(10):1444-1450 (Oct. 1993).				
	C9	Kawakami, M. et al., "Possible Mechanism of Painful Radiculopathy in Lumbar Disc Herniation," Clin. Orthop. 351:241-251(1998).				
	C10	Gordon, J.L., et al., "Metalloproteinase Inhibitors as Therapeutics," Clin. Exp. Rheumatol., 11(Supp 8): S91-S94 (1993).				
	CII	Johnson, W.H., et al., "Collagenase Inhibitors: Their Design and Potential Therapeutic Use," J. Enzyme Inhib., 2:1-22 (1987).				
9	C12	Möller, A. et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor α: In Vitro and In Vivo Application," Cytokine 2(3):162-169 (1990).				

EXAMINER DATE CONSIDERED			
CARELLA CONTRACTOR AND CONTRACTOR AN	Mulanus H Jalla	11-4-05	

PTO-1449 REPRODUCED	ATTORNEY DOCKET NO.		APPLICATION NO.		
	3518.1015-000		10/630,227		
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	1		FILING DATE July 30, 20	03	
October 11, 2005	EXAMINER	CONF	IRMATION NO.	GROUP	
(Use several sheets if necessary)	Lee, Betty L.	8291	<u> </u>	1647	

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
W.	Liang, CM., et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," Biochem. Biophys. Res. Comm. 137:847-854 (1986).							
	Meager, A., et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," Hybridoma 6(3):305-311 (1987).							
·		C15	Fendly et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," Hybridoma 6:359-370 (1987).					
		C16	Bringman, T.S., et al., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> 6(5):489-507 (1987).					
		C17	Hirai, M., et al., "Production and Characterization of Monoclonal Antibodies to Human Tumor Necrosis Factor," J. Immunol. Meth. 96:57-62 (1987).					
		C18	Schall, T., et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," Cell, 61:361-370 (1990).					
		C19	Loetscher, H., et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," Cell, 61:351-359 (1990).					
		C20	Corcoran, A., et al., "Characterization of Ligand Binding by the Human p55 Tumour-Necrosis-Factor Receptor," Eur. J. Biochem., 223:831-840 (1994).					
		C21	Engelmann, H. et al., "Two Tumor Necrosis Factor-Binding Proteins Purified From Human Urine," J. Biol. Chem., 265(3):1531-1536 (1990).					
		C22	Lesslauer, W., et al., "Recombinant Soluble Tumor Necrosis Factor Receptor Proteins Protect Mice from Lipopolysaccharide-Induced Lethality," Eur. J. Immunol., 21:2883-2886 (1991).					
		C23	Ashkenazi, A., et al., "Protection Against Endotoxic Shock by a Tumor Necrosis Factor Receptor Immunoadhesin," Proc. Natl. Acad. Sci. USA 88:10535-10539 (1991).					
J		C24	Peppel, K., et al., "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity," J. Exp. Med., 174:1483-1489 (1991).					

DATE CONSIDERED EXAMINER @PFDesktop\:ODMAMHODMA/HBSR03;iManage;470187;1

				311001 3 01
PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 3518.1015-000	APPLICATION NO. 10/630,227		
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October 11, 2005 (Use several sheets if necessary)	EXAMINER Lee, Betty L.	CONF 8291	IRMATION NO.	GROUP 1647

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
SH5	C25	Capon, D., et al., "Designing CD4 Immunoadhesins for AIDS Therapy," Nature, 337:525-531 (1989).					
	Kolls, J., et al., "Prolonged and Effective Blockade of Tumor Necrosis Factor Activity Through Adenovirus-Mediated Gene Transfer," Proc. Natl. Acad. Sci. USA 91:215-219 (1994).						
	C27	Butler, D., et al., "TNF Receptor Fusion Proteins are Effective Inhibitors of TNF-Mediated Cytotoxicity on Human KYM-1D4 Rhabdomyosarcoma Cells," Cytokine, 6(6):616-623 (1994).					
	C28	Baker, D., et al., "Control of Established Experimental Allergic Encephalomyelitis by Inhibition of Tumor Necrosis Factor (TNF) Activity within the Central Nervous System using Monoclonal Antibodies and TNF Receptor-Immunoglobulin Fusion Proteins," Eur. J. Immunol., 24:2040-2048 (1994).					
	C29	Zhang, C., et al., "Mitogen-activated Protein (MAP) Kinase Regulates Production of Tumor Necrosis Factor-α and Release of Arachidonic Acid in Mast Cells," J. Biol. Chem., 272(20): 13397-13402 (1997).					
	C30	Pargellis, C., et al., "Inhibition of p38 MAP Kinase by Utilizing a Novel Allosteric Binding Site," Nature Structural Biology, 9(4): 268-272 (2002).					
	C31	Chae, H.J., et al., "The p38 Mitogen-activated Protein Kinase Pathway Regulates Interleukin-6 Synthesis in Response to Tumor Necrosis Factor in Osteoblasts," Bone, 28(1): 45-53 (2001).					
	C32	Cirillo, P., et al., "The Non-Diaryl Heterocycle Classes of p38 MAP Kinase Inhibitors," Current Topics in Medicinal Chemistry, 2:1021-1035 (2002).					
	C33	Boehm, J. and Adams, J., "New Inhibitors of p38 Kinase," Exp. Opin, Ther. Patents, 10(1):25-38 (2000).					
	C34	Lee et al., "Inhibition of p38 MAP Kinase as a Therapeutic Strategy," Immunopharmacology, 47:185-2001 (2000).					
	C35	Brown, K., et al., "Gelatin/Chondroitin 6-Sulfate Microspheres for the Delivery of Therapeutic Proteins to the Joint," Arthritis. Rheum., 41(12):2185-2195 (1998).					
	C36	Burke, J.G., et al., "Intervertebral Discs Which Cause Low Back Pain Secrete High Levels of Proinflammatory Mediators," JBJS, 84-B(2):196-201 (2002).					

DATE CONSIDERED

EXAMINER

@PFDeskiop\:ODMA/MHODMA/HBSR05;IManage;470187;1

PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. APPLICATION 10/630,2		PLICATION NO. /630,227		
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	1		FILING DATE July 30, 2003		
October 11, 2005 (Use several sheets if necessary)	EXAMINER Lee, Betty L.	CONF 8291	IRMATION NO.	GROUP 1647	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AK5	C37	Gabay, C., "IL-1 Trap," Curr. Opin. Invest. Drugs, Curr. Drugs, London, GB, 4(5):593-597 (2003).
	C38	Dayer, J.M., "The Pivotal Role of Interleukin-1 in the Clinical Manifestations of Rheumatoid Arthritis," Rheumatology, Oxford University Press, London, GB, 42(Suppl 2):ii03-ii10 (2003).